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OCT 11

510(k) Summary of Safety and Effectiveness
Smith & Nephew Cannulated Screws and Washers

Submitted By:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	October 6, 2011
Contact Person:	Maureen Whitson, Senior Regulatory Affairs Specialist Tel: 901-399-6845, Fax 901-566-7568
Proprietary Name:	Smith & Nephew Cannulated Screws and Washers
Common Name:	Cannulated Screws and Washers
Device Classification Name and Reference:	21 CFR 888.3040 Smooth or threaded metallic bone fixation fastener and 21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories
Device Class:	Class II
Panel Code:	Orthopedics/ 87 - HWC and NDG

Device Description

The subject of this Traditional 510(k) premarket notification is to expand the indications of the already existing, cleared Smith & Nephew Cannulated Screws and Washers by adding osteotomies and arthrodesis. The subject devices are part of the Smith and Nephew Bone Plate System cleared under 510(k) number K993106 and K060736 with the same original indications but the subject 4.0mm, 5.5mm, 6.5mm, 7.0mm and 8.0mm cannulated screws and associated washers have additional indications independent of the Bone Plate System.

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The screws vary in diameter, length and thread length; have fluted screw tips for self-tapping and self-drilling and have a hexagonal screw heads. The screws may be used with bone washers to extend the surface area of the head if needed. These screws are cannulated to allow the screws to be accurately positioned with the use of a guidewire instrument. The device offering consist of diameters of 4.0mm, 5.5mm, 6.5mm, 7.0mm and 8.0mm in titanium alloy and stainless steel.

Smith & Nephew Cannulated Screw Size Ranges

Diameter	Length Range	Thread Length Range	Material
4mm	20mm - 70mm	8mm - 15mm	Ti
4mm	10mm - 70mm	5mm - 15mm and fully threaded	SS
5.5mm	20mm - 120mm	8mm - 32mm and fully threaded	Ti
5.5mm	20mm - 120mm	5mm - 15mm and fully threaded	SS
6.5mm	30mm - 180mm	22mm - 46mm and fully threaded	Ti
6.5mm	30mm - 150mm	22mm - 46mm and fully threaded	SS
7mm	30mm - 150mm	16mm - 32mm and fully threaded	Ti
7mm	30mm - 150mm	16mm - 32mm and fully threaded	SS
8mm	40mm - 180mm	22mm - 46mm and fully threaded	Ti
8mm	40mm - 180mm	22mm - 180mm and fully threaded	SS

Summary of Cannulated Screw Accessory Washers

Accessory Device	Type	Size Range	Material
Washers	Round	4.0mm to 8.0mm Internal Diameter	Ti and SS
Washer	Butterfly	8.0mm Internal Diameter and Overall Length 21.7mm	Ti and SS

Intended Use

Bone plates and screws from the Smith and Nephew Bone Plate System are used for adult and pediatric patients as indicated for pelvic, small, and long bone fracture fixation. Indications for use include, fractures of the tibia, fibula, femoral condyle, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, middle hand and middle foot bones; treatment of the calcaneus; hip arthrodesis, and provisional hole fixation.

The 4.0mm Cannulated Screws and associated washers are additionally intended for arthrodesis and osteotomies of small bones and small joints, including scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, patella, ulnar styloid, capitellum, radial head and radial styloid.

The 5.5mm, 6.5mm, 7.0mm, and 8.0mm Cannulated Screws and associated washers are additionally intended for reconstruction, osteotomy, and arthrodesis of various bones and bone fragments appropriate for the size of the device including joint fusions (arthrodesis) in the foot and ankle.

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Technological Characteristics

The Smith & Nephew Cannulated Screws and Washers are very similar to legally marketed devices cleared under K090675, K080943, K063298, K102903, K021932, K052483, and K003496. When compared to the predicates, the devices share very similar indications for use and intended use, are manufactured from similar materials and incorporate similar technical design characteristics.

A review of the mechanical data indicates that the Smith & Nephew Cannulated Screws are capable of withstanding expected *in vivo* loading without failure. The performance bench testing consisted of a three point bend fatigue, static torsional and axial pullout bend test, comparing the S&N 4.0mm screws (Ti and SS) to the S&N 3.0mm SS screw and the results show the subject screw would perform equal or better that the predicate screws. The performance bench testing also consisted of a four point bend fatigue, static torsional and axial pullout bend test, comparing the S&N 5.5mm screws (Ti and SS) to the Synthes titanium 4.5mm screw and the results show the subject screws would perform equal or better than the predicate screws.

Substantial Equivalence Information:

The substantial equivalence of the Smith & Nephew Cannulated Screws and Washers is based on its similarities in indications for use, design features, operational principles, and material composition to the devices listed below.

Manufacturer	Description	Submission Number
Smith & Nephew	Smith & Nephew 3.0 Cannulated Screw, SS	K090675
Synthes	4.5 Headless Compression Screw (cannulated), Ti	K080943
Osteomed	Osteomed Headless Cannulated Screw System	K063298
Pioneer	Pioneer Cannulated Screw System	K102903
Synthes	Synthes 6.5 mm Cannulated Screw	K021932
Synthes	Synthes Spherical Washers	K052483
Pioneer	Cannulated Screw System, Washer	K003496

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Similarities and Difference between the Subject Devices and predicate Devices

Similarities

	Similarities of Subjects to Predicates
Design	Similar in dimensions (screw diameter, screw length)
Features	Both predicate and subject are cannulated, both have varying thread lengths, both are offered with accessory bone screw washers
Material	Both are offered in SS and Ti Alloy
Indications for Use	Both are indicated for fractures, osteotomies and arthrodesis of various small bones and joints

Differences

	Differences of Subjects to Predicates	Rationale why this difference does not affect the Safety and Effectiveness
Design	Screw head dimensions may have slight size differences and some may be smooth and others may be threaded or "headless"	Headless screws are used for counter-sinking to prevent the implanted screw from sitting too proud on the bone surface and are for surgeon preference. The screw head size does not affect the performance of the implanted screw in regard to the mechanical stresses on the shaft of the screws.
Design	Varying screw thread length	The thread lengths do not affect the mechanical stresses of the implanted screws. Their application is chosen based on surgeon preference and on what kind of fracture, osteotomy or arthrodesis in which the screw will be used.
Chemical Composition	The predicate Synthes 4.5mm Ti alloy screw is made from Ti -6Aluminum -7 Niobium instead of Ti 6 Aluminum- 4Vanadium	The niobium was substituted for the vanadium as the beta stabilizing element in this alloy. According to the manufacturer of the raw material, the mechanical properties are almost identical and it is a common alloy used in orthopedic implants. Our bench testing shows the subject screws performed equal or better than the predicate screw made with this material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Smith & Nephew, Inc.
% Ms. Maureen Whitson
Senior Regulatory Affairs Specialist
7135 Goodlett Farms Parkway
Cordova, Tennessee 38106

OCT 1 1 2011

Re: K111994
Trade/Device Name: Cannulated Screws and Washers
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, NDG
Dated: July 12, 2011
Received: July 13, 2011

Dear Ms. Whitson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known): K111994

Device Name: Cannulated Screws and Washers

Indications for Use:

Bone plates and screws from the Smith and Nephew Bone Plate System are used for adult and pediatric patients as indicated for pelvic, small, and long bone fracture fixation. Indications for use include, fractures of the tibia, fibula, femoral condyle, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, middle hand and middle foot bones; treatment of the calcaneus; hip arthrodesis, and provisional hole fixation.

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Prescription Use (Part 21 CFR 801 Subpart D)	X	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael Chen for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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